

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and)
EDWARDS LIFESCIENCES, LLC,)
Plaintiffs,)
vs.) C.A. No. 08-091-GMS
COREVALVE, INC.,) JURY TRIAL DEMANDED
Defendant.)

COREVALVE, INC.,)
Counterclaimant,)
vs.)
EDWARDS LIFESCIENCES AG and)
EDWARDS LIFESCIENCES, LLC,)
Counterdefendants,)

)

**DEFENDANT COREVALVE, INC.'S ANSWER AND AFFIRMATIVE DEFENSES
TO COMPLAINT AND COUNTERCLAIMS FOR DECLARATORY JUDGMENT
OF PATENT NONINFRINGEMENT AND INVALIDITY**

Defendant CoreValve, Inc. ("CoreValve"), by the undersigned attorneys, hereby responds to the allegations and averments in the Complaint of Edwards Lifesciences, AG and Edwards Lifesciences LLC (collectively "Edwards"), filed on February 12, 2008 ("Complaint"), as follows:

JURISDICTION AND VENUE

1. Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, CoreValve does not contest the jurisdictional and venue allegations of Paragraph 1 but denies that Edwards has any cause of action against CoreValve and that Edwards is entitled to any relief pursuant to its Complaint.

THE PARTIES

2. CoreValve has insufficient information to admit or deny the allegations contained in Paragraph 2 and therefore denies the allegations.

3. CoreValve admits the allegations contained in Paragraph 3.

4. CoreValve has insufficient information to admit or deny the allegations contained in Paragraph 4 that Edwards Lifesciences, AG is the assignee of U.S. Patent Nos. 5,411,552, 6,168,614, and 6,582,462, and therefore denies the allegations. CoreValve denies the remaining allegations of Paragraph 4.

5. CoreValve has insufficient information to admit or deny the allegations contained in Paragraph 5 and therefore denies the allegations.

6. CoreValve admits the allegations contained in Paragraph 6.

7. In response to Paragraph 7, CoreValve admits that it manufactures in the United States heart valve prostheses known as the "ReValving System" but denies the remaining allegations contained in Paragraph 7.

8. In response to Paragraph 8, CoreValve admits that it has obtained European CE mark approval for its ReValving System and, further, that it is currently offering its ReValving System for clinical evaluation in Europe. CoreValve denies the remaining allegations contained in Paragraph 8.

FIRST CAUSE OF ACTION

(For Infringement of the '552 Patent)

9. CoreValve incorporates by reference its answers to the allegations contained in Paragraphs 1 through 8.

10. In response to Paragraph 10, CoreValve admits that U.S. Patent No. 5,411,552 entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis" (the "'552 Patent") issued on May 2, 1995. On information and belief, CoreValve denies that the '552 Patent was duly and legally issued as alleged in Paragraph 10. CoreValve has insufficient information to form a belief as to the truth or falsity of the remaining allegations of Paragraph 10 and therefore denies the allegations.

11. CoreValve denies the allegations of Paragraph 11.

12. CoreValve denies the allegations of Paragraph 12.

13. CoreValve denies the allegations of Paragraph 13.

SECOND CAUSE OF ACTION

(For Infringement of the '614 Patent)

14. CoreValve incorporates by reference its answers to the allegations contained in Paragraphs 1 through 13.

15. In response to Paragraph 15, CoreValve admits that U.S. Patent No. 6,168,614 entitled "Valve Prosthesis for Implantation in the Body" (the "'614 Patent") issued on January 2, 2001. On information and belief, CoreValve denies that the '614 Patent was duly and legally issued as alleged in Paragraph 15. CoreValve has insufficient information to form a belief as to the truth or falsity of the remaining allegations of Paragraph 15 and therefore denies the allegations.

16. CoreValve denies the allegations of Paragraph 16.

17. CoreValve denies the allegations of Paragraph 17.
18. CoreValve denies the allegations of Paragraph 18.

THIRD CAUSE OF ACTION
(For Infringement of the '462 Patent)

19. CoreValve incorporates by reference its answers to the allegations contained in Paragraphs 1 through 18.
20. In response to Paragraph 20, CoreValve admits that U.S. Patent No. 6,582,462 entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis" (the "'462 Patent") issued on June 24, 2003. On information and belief, CoreValve denies that the '462 Patent was duly and legally issued as alleged in Paragraph 20. CoreValve has insufficient information to form a belief as to the truth or falsity of the remaining allegations of Paragraph 20 and therefore denies the allegations.

21. CoreValve denies the allegations of Paragraph 21.
22. CoreValve denies the allegations of Paragraph 22.
23. CoreValve denies the allegations of Paragraph 23.

AFFIRMATIVE DEFENSES

24. CoreValve, without admissions as to burden of proof, asserts the following affirmative defenses to the Complaint.

FIRST AFFIRMATIVE DEFENSE

25. CoreValve has not infringed, induced others to infringe, or contributed to the infringement of any valid claim of the '552 Patent and does not now do so.

SECOND AFFIRMATIVE DEFENSE

26. CoreValve is informed and believes, and thereupon alleges, that the '552 Patent is invalid for failure to meet one or more of the requirements of patentability under United States Code Title 35, including, without limitation, one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE

27. CoreValve has not infringed, induced others to infringe, or contributed to the infringement of any valid claim of the '614 Patent and does not now do so.

FOURTH AFFIRMATIVE DEFENSE

28. CoreValve is informed and believes, and thereupon alleges, that the '614 Patent is invalid for failure to meet one or more of the requirements of patentability under United States Code Title 35, including, without limitation, one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112.

FIFTH AFFIRMATIVE DEFENSE

29. CoreValve has not infringed, induced others to infringe, or contributed to the infringement of any valid claim of the '462 Patent and does not now do so.

SIXTH AFFIRMATIVE DEFENSE

30. CoreValve is informed and believes, and thereupon alleges, that the '462 Patent is invalid for failure to meet one or more of the requirements of patentability under United States Code Title 35, including, without limitation, one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112.

SEVENTH AFFIRMATIVE DEFENSE

31. Each and every one of Edwards' claims for relief fails to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE

32. CoreValve has not infringed any claim of the '552, '614 or '462 patents because, by reason of the provisions of 35 U.S.C. §271(e)(1), no act of CoreValve alleged by Edwards to be an act of infringement in the Complaint is an act of infringement.

NINTH AFFIRMATIVE DEFENSE

33. Edwards is not entitled to injunctive relief because any alleged injury to Edwards is neither immediate nor irreparable, and should Edwards prevail in this action Edwards has an adequate remedy at law.

WHEREFORE, CoreValve prays for the following relief:

1. That Edwards take nothing by way of its Complaint, that judgment be entered in favor of CoreValve, and the Complaint be dismissed with prejudice;
2. That this is an exceptional case within the meaning of 35 U.S.C. § 285 and that Edwards be required to pay CoreValve's costs of suit incurred in defense of this action including reasonable attorneys' fees; and
3. Such other relief as the Court deems just and proper.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs/Counterdefendants Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively "Edwards") Defendant/Counterclaimant CoreValve alleges as follows:

JURISDICTION AND VENUE

1. This Court has federal subject matter jurisdiction over the Counterclaims asserted herein pursuant to 35 U.S.C. §§ 1331 and 1338.
2. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

PARTIES

3. CoreValve is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Jenner, Irvine, California 92618.
4. On information and belief, Plaintiff/Counterdefendant Edwards Lifesciences AG is a corporation organized and existing under the laws of Switzerland and having its principal place of business in St.-Prex, Switzerland.
5. On information and belief, Plaintiff/Counterdefendant Edwards Lifesciences LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Edwards Way, Irvine, California 92614.

FIRST CLAIM FOR RELIEF:

DECLARATORY JUDGMENT OF PATENT INVALIDITY ('552 PATENT)

6. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 5 of these Counterclaims as if set forth in full herein.
7. This Counterclaim arises under the patent laws of the United States and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).
8. An actual controversy exists between Edwards and CoreValve by virtue of the allegations of the Complaint and the Answer thereto as to whether any claim of U.S. Patent No. 5,411,552 (the "552 Patent") is valid and infringed by CoreValve.

9. One or more claims of the '552 Patent are invalid for failing to meet one or more of the applicable statutory requirements of Part II of Title 35 of the United States Code as a condition of patentability, including §§ 102, 103 and/or 112.

10. To resolve the controversy between the parties the Court should declare the '552 patent invalid.

SECOND CLAIM FOR RELIEF:

DECLARATORY JUDGMENT OF PATENT NONINFRINGEMENT ('552 PATENT)

11. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 10 of these Counterclaims as if set forth herein in full.

12. This Counterclaim arises under the patent laws of the United States and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).

13. Edwards has filed suit alleging infringement by CoreValve of the '552 Patent. CoreValve denies infringement. An actual justiciable controversy therefore exists between the parties as to the alleged infringement of the '552 Patent.

14. No product made, used, offered for sale, or sold in the United States or imported into the United States by CoreValve has infringed or is infringing any valid claim of the '552 Patent.

15. To resolve the controversy between the parties the Court should declare that CoreValve has not infringed any valid claim of the '552 Patent.

THIRD CLAIM FOR RELIEF:

DECLARATORY JUDGMENT OF PATENT INVALIDITY ('614 PATENT)

16. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 15 of these Counterclaims as if set forth herein in full.

17. This Counterclaim arises under the patent laws of the United States and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).

18. An actual controversy exists between Edwards and CoreValve by virtue of the allegations of the Complaint and the Answer thereto as to whether any claim of U.S. Patent No. 6,168,614 (the "614 Patent") is valid and infringed by CoreValve.

19. One or more claims of the '614 Patent are invalid for failing to meet one or more of the applicable statutory requirements of Part II of Title 35 of the United States Code as a condition of patentability, including §§ 102, 103 and/or 112.

20. To resolve the controversy between the parties the Court should declare the '614 patent invalid.

FOURTH CLAIM FOR RELIEF:

DECLARATORY JUDGMENT OF PATENT NONINFRINGEMENT ('614 PATENT)

21. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 20 of these Counterclaims as if set forth herein in full.

22. This Counterclaim arises under the patent laws of the United States and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).

23. Edwards has filed suit alleging infringement by CoreValve of the '614 Patent. CoreValve denies infringement. An actual justiciable controversy therefore exists between the parties as to the alleged infringement of the '614 Patent.

24. No product made, used, offered for sale, or sold in the United States or imported into the United States by CoreValve has infringed or is infringing any valid claim of the '614 Patent.

25. To resolve the controversy between the parties the Court should declare that CoreValve has not infringed any valid claim of the '614 Patent.

FIFTH CLAIM FOR RELIEF:

DECLARATORY JUDGMENT OF PATENT INVALIDITY ('462 PATENT)

26. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 25 of these Counterclaims as if set forth herein in full.

27. This Counterclaim arises under the patent laws of the United States and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).

28. An actual controversy exists between Edwards and CoreValve by virtue of the allegations of the Complaint and the Answer thereto as to whether any claim of U.S. Patent No. 6,582,462 (the "'462 Patent") is valid and infringed by CoreValve.

29. One or more claims of the '462 Patent are invalid for failing to meet one or more of the applicable statutory requirements of part II of Title 35 of the United States Code as a condition of patentability, including §§ 102, 103 and/or 112.

30. To resolve the controversy between the parties the Court should declare the '462 Patent invalid.

SIXTH CLAIM FOR RELIEF:

DECLARATORY JUDGMENT OF PATENT NONINFRINGEMENT ('462 PATENT)

31. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 30 of these Counterclaims as if set forth herein in full.

32. This Counterclaim arises under the patent laws of the United States and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).

33. Edwards has filed suit alleging infringement by CoreValve of the '462 Patent. CoreValve denies infringement. An actual justiciable controversy therefore exists between the parties as to the alleged infringement of the '462 Patent.

34. No product made, used, offered for sale, or sold in the United States or imported into the United States by CoreValve has infringed or is infringing any valid claim of the '462 Patent.

35. To resolve the controversy between the parties the Court should declare that CoreValve has not infringed any valid claim of the '462 Patent.

SEVENTH CLAIM FOR RELIEF:

AWARD OF ATTORNEYS' FEES PURSUANT TO 35 U.S.C. § 285

36. CoreValve incorporates by reference and re-alleges Paragraphs 1 through 35 of these Counterclaims as if set forth herein in full.

37. Edwards knew or should have known that the '552, '614, and '462 Patents were not infringed and/or were invalid. In light of Edwards' initiation and maintenance of this lawsuit, this is an exceptional case under 35 U.S.C. § 285. Thus, CoreValve is entitled to an award of its reasonable attorneys' fees.

DEMAND FOR JUDGMENT

WHEREFORE, CoreValve prays as follows:

A. That judgment be entered declaring that one or more claims of the '552 Patent are invalid.

B. That judgment be entered declaring that CoreValve has not directly or indirectly infringed any valid claim of the '552 Patent.

- C. That judgment be entered declaring that one or more claims of the '614 Patent are invalid.
- D. That judgment be entered declaring that CoreValve has not directly or indirectly infringed any valid claim of the '614 Patent.
- E. That judgment be entered declaring that one or more claims of the '462 Patent are invalid.
- F. That judgment be entered declaring that CoreValve has not directly or indirectly infringed any valid claim of the '462 Patent.
- G. That CoreValve be awarded its costs of suit.
- H. That this is an exceptional case within the meaning of 35 U.S.C. § 285 entitling CoreValve to reasonable attorneys' fees.
- I. For such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

CoreValve hereby requests a trial by jury on all issues herein so triable.



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Dated: April 4, 2008

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2008, I caused to be served by electronic service and hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on April 4, 2008, the foregoing document was sent via Federal Express to the following non-registered participants:

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